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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/736,868

12/16/2003

Aaron Solomon

NWESTERN-08451

9086

7590

12/23/2005

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EXAMINER

PRIEBE, SCOTT DAVID

ART UNIT

PAPER NUMBER

1633

DATE MAILED: 12/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/736,868	Applicant(s) SOLOMON ET AL.	
	Examiner Scott D. Priebe, Ph.D.	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12 is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>20051205</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

The PTO-1449 form filed 12/5/05 is improper with respect to the citations of the non-patent documents because the citations did not include the titles of the articles as required (see MPEP 609, III.A.A(1).) These references have been considered, as indicated by the examiner's initials on the PTO-1449 forms. However, the citations have been crossed out on the forms to indicate they will not be printed on the face of a patent. Should Applicant wish these reference citations be printed on the face of a patent, Applicant should provide a corrected PTO-1449 containing complete bibliographic citations.

Claim Rejections - 35 USC § 112

Claims 1-8 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record set forth in the Office action of 7/28/05. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's arguments filed 12/5/05 have been fully considered but they are not persuasive. The amendment to the claims only partially overcomes the grounds of rejection. The

Art Unit: 1633

claims still embrace all nematodes and possibly all osmotic stress resistant genes (see rejection under 35 USC 112, 2nd para.) without restriction, whereas the specification at most adequately describes *C. elegans* mutants in OSR-1 that have decreased sensitivity to osmotic desiccation.

Applicant asserts that the specification (page 17, line 3, through page 19, line 4; page 45, lines 4-15; and page 59, lines 8-22) teaches that OSR-1 sequence taught by the present invention permit one to generate mutant OSR-1 homologous genes and nematodes harboring such genes how to generate mutant nematodes with reduced or increased sensitivity to osmotic desiccation stress via altering (e.g., mutating) an OSR-1 homologous gene. In response, pages 17-19 merely defines terms used in the specification and does not describe the invention. Page 45 describes how one might detect polymorphism in an OSR-1 gene in a nematode, assuming one was in possession of the corresponding DNA of the OSR-1 gene of that nematode. However, the specification describes such DNA only from the OSR-1 gene of *C. elegans*. Page 59 suggests making transgenic animals, such as nematodes, that have increased or decreased expression of OSR-1 mRNA. The specification does not suggest that any such transgenic animals had been made or what the result of such transgenesis would be with respect to osmotic desiccation sensitivity or resistance. Also, except for a knock-out of the OSR-1 gene, such transgenes would not be mutations in the OSR-1 gene.

Whether or not one of skill in the art would be able to make nematodes that carried mutation that affected osmotic stress resistance or sensitivity, and then screen them to see if they had a mutation in a homologue of the *C. elegans* OSR-1 gene is not at issue here. Rather the issue is whether the specification contains a written description of a genus of collections of mutant nematodes or OSR-1 genes of other nematodes that is adequate to demonstrate to one of

Art Unit: 1633

skill in the art that Applicant was in possession of such a genus. Description of a method that could potentially be used to make a product does not demonstrate that one is in possession of the product made. See *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997) and *University of Rochester v. G.D. Searle & Co.* 69 USPQ2d 1886 (CA FC 2004).

Furthermore, the claims permit embodiments, including where the nematode is *C. elegans*, where the mutation increases sensitivity to osmotic desiccation. In contrast, the specification teaches that all *C. elegans* mutants in OSR-1 obtained had decreased sensitivity to osmotic desiccation. Suggesting that it might be possible to mutate OSR-1 to increase sensitivity to osmotic desiccation, especially when there is no evidence that such is possible, does not place one in possession of such mutants.

On page 6 of the reply, Applicant refers to "Appendix I" referring to *Strongyloides ratti*. However, no such appendix has been made of record. Furthermore, the specification does not mention *Strongyloides ratti*, much less describe a collection of mutants readable of the instant claims.

Claims 6-8 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for the reasons of record set forth in the Office action of 7/28/05. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's arguments filed 12/5/05 have been fully considered but they are not persuasive. The replacement of "treating" with "contacting" in claim 6 does not change the scope

Art Unit: 1633

of the claim, which still has the same method step of “exposing said host” to the composition of claim 1. The amendment of claim 1, limits the composition to at least nematodes mutant in an OSR-1 gene, or possibly a generic OSR gene (see rejection under 35 USC 112, 2nd para.).

Applicant asserts that the specification (page 59, line 23, to page 60, line 3) teaches uses in multiple settings including research and therapeutic applications. However, the description at page 59, lines 23-29, is not directed to a method of contacting a host organism with the collection of mutant nematodes, and the minimal and inadequate disclosure on page 59, line 30, to page 60, line 3, has already been addressed in the rejection. Applicant simply avoids directly addressing the grounds of rejection, and fails to provide evidence or sound scientific reasoning that those grounds are in error.

Claims 1-8 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms "reduce" and “increase” are relative terms which renders the claim indefinite. The terms "reduce" and “increase” are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree. The standard, e.g. a reference nematode, to which the mutant is compared to determine whether it has reduced or increased stress desiccation stress resistance is not recited in claims or described in the specification. Thus, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim

Art Unit: 1633

does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 1 and 2 recite the broad recitation "osmotic stress resistant", and the claim also recites "OSR-1" which is the narrower statement of the range/limitation.

Applicant has not addressed this rejection of claim 2, and claim 1 has been amended to include similar language. In short, it is unclear if the claims are limited to mutants in OSR-1 specifically, or if the OSR-1 is recited simply as an example of an generic OSR gene. This rejection would be overcome by replacing "osmotic resistant (OSR-1) gene" with --osmotic resistant-1 gene (OSR-1)-- or --OSR-1 (osmotic resistant-1) gene--. With respect to recitation of "reduce" and "increase," Applicant asserts that these terms are defined at page 82, line 26, to page 83, line 5. However, this part of the specification does not define these terms, it discusses the osmotic stress sensitivity of one particular mutant nematode as compared to a wild type nematode in a non-limiting example.

Claim Rejections - 35 USC § 102 & 103

Claims 1, 3-6, and 8 remain rejected under 35 U.S.C. 102(b) as being anticipated by Piggott et al. (Nematol. 2(5): 561-566, 2000) for the reasons of record set forth in the Office action of 7/28/05.

Claims 1 and 3-5 remain rejected under 35 U.S.C. 102(b) as being anticipated by Ogg et al. (Nature 389: 994-999, Oct. 1997) as evidenced by the instant specification for the reasons of record set forth in the Office action of 7/28/05.

Claims 1, 3-6, and 8 remain rejected under 35 U.S.C. 102(b) as being anticipated by O'Leary et al. (Fundam. Appl. Nematol. 20(2): 197-205, 1997) for the reasons of record set forth in the Office action of 7/28/05.

Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Leary et al. (Fund. Appl. Nematol. 20(2): 197-205, 1997) for the reasons of record set forth in the Office action of 7/28/05.

Applicant's arguments filed 12/5/05 have been fully considered but they are not persuasive. Applicant argues that the cited prior art does not disclose nematodes mutant in an OSR-1 gene. However, the features upon which applicant relies (i.e., mutation in an OSR-1 gene) are not clearly recited in the rejected claim(s) for the reasons set forth in the rejection under 35 USC 112, 2nd para. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988

Art Unit: 1633

F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). These rejections would be overcome by the same amendments suggested above to overcome the rejection under 35 USC 112, 2nd para., i.e. by clearly and unequivocally limiting the mutant nematodes to those with mutations in their OSR-1 gene.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

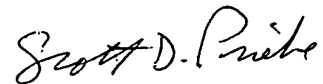
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe, Ph.D. whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1633

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in cursive script that reads "Scott D. Priebe".

Scott D. Priebe, Ph.D.
Primary Examiner
Art Unit 1633